Docket No.: NEN-22902/16 (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Blas Cerda

Application No.: 10/539,273 Confirmation No.: 8503

Filed: June 16, 2005 Art Unit: 1651

For: MASS SPECTROMETRY METHODS FOR Examiner: L. E. Barnhart

SIMULTANEOUS DETECTION OF

METABOLIC ENZYME ACTIVITY AND

METABOLITE LEVELS

RESPONSE TO ELECTION OF SPECIES REQUIREMENT

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the Restriction Requirement mailed April 18, 2008, Applicant hereby elects the species covered by (a) neonate or newborn, as in claims 6-9 and 33-36; (d) inborn error of metabolism as in claims 10, 11, 37 and 38; (l) biotinidase, as in claims 12-14 and 39-41; and (m) amino acid, as in claims 16, 17, 43 and 44, for further prosecution of the subject application.

Applicant makes the elections with traverse. The Examiner finds the species lacking "the same or corresponding special technical features" because "[p]ursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents."

Applicant notes that the PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2) cited by the Examiner is believed to be directed specifically at "Markush grouping' and that none of claims 6-9, 10, 11, 13, 14, 16, 17, 33-38, 40, 41, 43, or 44 is believed to be a Markush-style claim. Furthermore, each of these claims is in dependent form and Applicant notes the guidance in the MPEP stating that

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims...If the independent claims avoid the prior art and satisfy the requirement

Application No.: 10/539,273 2 Docket No.: NEN-22902/16

of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims." MPEP, 8th Ed., revision 6, 1850, Section II, para. 6 and 7.

With regard to claims 12 and 39 which are believed to be Markush-style claims, Applicant notes the requirement that the "alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains" and that a "recognized class of chemical compounds" is one for which "there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention." (MPEP, 8th Ed., revision 6, 1850, Section IIIB, para. 2 and 4) Claims 12 and 39 describe "metabolically indicative enzymes" which will behave in the same way in the context of the methods described in the independent claims, that is, the metabolically indicative enzymes act "on a corresponding substrate to produce at least one product." The MPEP further states that "[t]he fact that the alternatives of a Markush grouping can be differently classified should not, taken alone, be considered to be justification for a finding of a lack of unity of invention." (MPEP, 8th Ed., revision 6, 1850, Section IIIB, para. 5) Still further, claims 12 and 39 are dependent claims and, as noted above, "[i]f the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims."

Applicant therefore respectfully submits that no basis for a lack of unity of invention has been established and requests withdrawal of the requirement and examination of all claims and species.

Questions regarding this application may be directed to the undersigned attorney at the telephone and facsimile numbers provided.

Dated: June 18, 2008

Respectfully submitted,

Julie K. Staple (Reg. No. 50,434)

GIFFORD, KRASS, SPRINKLE et al.

2701 Troy Center Drive, Suite 330

Post Office Box 7021

Troy, Michigan 48007-7021

(734) 913-9300 (734) 913-6007 (Fax)